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December 25.1998
Mr. Fu Sheng Jin
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Washington DC 20006
Tel: (202)775-1108

Dr. Elizabeth Yetley
Office of Special Nutrition
HFS-450
200 C Street, S. W.
Washington, D. C. 20204

Dear Dr. Elizabeth Yetley,

2001 3/4/98 8 83:12
According to " Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about "Watermelon frost mouth-throat lozenge" dietary supplement to notice of structure and function class for 30 days post-market. Although it has been delivered to the United State of America before October 15,1994, we need to revise the" watermelon frost mouth-throat lozenge tablet " labeling again. It is necessary to send "Watermelon frost mouth-throat" lozenge papers to FDA for petitioner.

Watermelon frost mouth-throat lozenge
Manufactured by Gui Lin San Jin Pharmaceutical Group Co, Gui Lin city,China
Distributed by Chinese Herb Center, Inc.

I included following data for Watermelon frost mouth-throat lozenge for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours

Manager Mr. Fu Sheng Jin

Fu Sheng Jin

A petitioner to FDA about watermelon frost mouth-throat lozenge

A. Identity; Composition; Physical, Chemical and Organoleptic Characteristics

1. Name of Dietary supplement

- Chemical name: not available
- Common name: Watermelon frost mouth-throat lozenge
- CAS registry number: not available

2. Chemical identity:

- Structure formula: not available
- Molecular weight: not available
- Molecular formula: not available

3. Organoleptic properties:

- Appearance: powder
- Color: light brown
- Taste: bitter

4. Physical and Chemical properties:

- pH: ND
- Melting point: ND
- Water content: ND
- Solubility: soluble in water.
- Specifications:

Watermelon frost mouth-throat lozenge is manufactured by Gui Lin San Jin Pharmaceutical Group Co. They sent 30 samples of San Jin extract powder (the batch number 9703103) for analysis, and they received the certification from the Department of TCM Health, Research Institute of Drug and Biological Productive Health, Beijing, China. The average data measured per tablet are listed below.

(1) Content:

(a) Nutrition facts:

Serving size 2 tablets (contains 210mg/tablet); Server 2 tablets

Amount per serving

Calories ND

Calories from fat :ND

		DRVs	% Daily value*
Total fat	ND	65g	ND
Cholesterol	ND		
Sodium	ND	2.4mg	ND
Total carbohydrate	ND	300g	ND
Protein	ND	50g	ND
Soft fiber	ND	25g	ND
Vitamin A		Vitamin C --	
Thiamin		Riboflavin --	
Niacin		Vitamin B6 --	
Vitamin E		Zinc	
Calcium		Iron	

* Percent daily values are based on a 2,000 calorie

(b) Average amount of nutrition facts in one of 30 samples of the Watermelon frost mouth-throat lozenge.

Reduce sugar	ND	Total sugar	ND	Carbohydrate	ND
Protein	ND	Fat	ND		
Fiber	ND	Cholesterol	ND	Others	ND

(c) Average metals contain in one of 30 sample of the Watermelon frost mouth-throat lozenge

Sodium	ND	Calcium	ND	Iron	ND
Phosphorous	ND	Magnesium	ND	Zinc	ND
Copper	ND	Iodine	ND	Potassium	ND

(d) Average vitamin contain in one of 30 samples of the Watermelon frost mouth-throat lozenge

Carotene	ND	Vitamin C	ND	Vitamin B1	ND
Niacin	ND	Vitamin A	ND	Vitamin D	ND
Vitamin E	ND				

(e) Average amount of impurities, toxins and pesticides in one of 30 sample of the Watermelon frost mouth-throat lozenge

Heavy metal	Lead (Pb)	<0.5ug/g
	Arsenic (As)	0.5ug/Kg
	Cadmium (Cd)	0.1ug/g
	Mercury (Hg)	0.01ug/g
Others	Nitrite	ND
	Nitrate	ND

(f) Other toxins

Aflatoxin 9ug/Kg

Mycotoxin: ND

(g) Contaminated pesticides such as 666 (0.04 ug/g) and DDT (0.02ug/g) in 30 sample of the Watermelon frost mouth-throat lozenge.

The amount of impurities and pesticides measured are lower than that specified in the FDA standard

(2) Components:

The Watermelon frost mouth-throat lozenge per tablet contains watermelon frost extract and of borneol extract.

Method of measurement used in above tests:

1. All productive metals in extract powder are measured by following methods:
2. Cadmium, Lead, and Mercury are measured by atomic absorption spectrophotometric method.
3. Arsenic is measured by Silver salt methods.
4. 666 and DDT are measured by gas chromatographic method.
5. Components are measured by high pressure liquid chromatographic method.

All nutritional indexes of method numbers have been referenced from " the methods of analysis for nutrition labeling," 1993 by AOAC INTERNATIONAL.

B. Intended use; projected average daily intake of Watermelon frost mouth-throat lozenge; proposed labeling

1. Amount of Watermelon frost mouth-throat lozenge proposed for use in the United States

Projected marketing figures for Water frost mouth-throat lozenge tablet have not been determined at this time.


2. Intended usage

Watermelon frost mouth-throat tablet is intended for use as a throat dietary supplement. (1).

3. Calculation of expected intake and daily consumption of Watermelon frost mouth-throat tablet:

From information given by Gui Lin San Jin Pharmaceutical group Co, the tablet is to be taken six times a day, two tablets each time. Each tablet weights 210mg, and this projects a daily consumption of 2520mg and yearly consumption of 919.8 g for an adult.

4.0. Tablet labeling

Recommended use Take 6 times a day, 2 tablets each time after meal. Each capsule contains 210 mg extract powder.	100% Natural Chinese Herbs
INGREDIENTS: watermelon frost; borneol etc.	Watermelon frost mouth-throat lozenge
No artificial color, flavors or preservatives are added. No additives.	20 tablets (210 mg each)
Store at a cool & dry location	Manufactured by Gui Lin San Jin Pharmaceutical Group Co, Gui lin, China
Batch No:	Distributed by Chinese Herb Products, Inc.
MFG date:	2025 Eye Street, NW Suite 507, Washington, DC 20006
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C. The Method and result of intended Effect:

report from experiment data, Watermelon frost mouth-throat tablet is a throat dietary supplement.

D. Safety investigations (Toxicological studies)

1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used watermelon frost for uncomfortable throat. This method has been kept till today and its efficacy is further improved by modern scientific studies. (1). Now Watermelon frost mouth-throat lozenge is manufactured with an unique process that preserves and concentrates the richest component. Already there are over millions people in the world taking watermelon frost mouth-throat lozenge every day. Also watermelon frost mouth-throat lozenge is delivered to many parts of the world, such as Asia, Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Also it has been delivered to the United States of America before October 15, 1994. Therefore it is considered as GRAS.

According to reports based on research experiments, using 5% alcohol extracts derived from two hundred selected varieties of commonly used medical herbs, when the extracts were forced to male white mice using the Linchofield and Wilcoxon method, in order to determine the LD 50 of each herb. However, for most commonly used medical herbs and formulas, the safe dosage was found to be relatively high, with the exception of raw Radix Aconniti Kusenezoffii and Semen Strychni. (2). Two component of watermelon frost mouth-throat lozenge is one of most popular Chinese herb. They report that LD-50 is the dose of 7.5g/Kg of watermelon frost tablet(1). For a person weighting 60 kilograms, The recommended usage for watermelon frost mouth-throat extract is 2520mg per day. That is the 2520mg per day/60 Kg=42mg/KG. when taken in normal dosage, watermelon frost mouth-throat has almost no toxicity(1). The recommended usage for watermelon extract is 2520mg per day; this dosage does not present any safety concerns.

2. Acute toxicity test for watermelon frost mouth-throat lozenge

Animal species: Little white mice, Kun ming species of average weight 20-22g, half male and half female is supplied by the animal room of the Academy of Traditional Chinese Medicine in Guang xi. (Certification by Medical Animal Center, China). The acute toxicity test has been done by Department of Pharmacology, Gui Lin Medical University and Gui Lin San Jin Pharmaceutical Group, Co.(1)

The acute toxicity experiment proved that 40 white mice are divided four groups, each group contains 5 male and 5 female. 1 time ingestion of watermelom frost extract (the dose is 9.0g raw herb /Kg body weight). After

observing 7 days, one mouse dies at 4th hour; one at 6th hour one at 12th hour; two at 24th hour; 5 mice survival. they measure LD50 dose=7.5g/Kg of watermelon frost extract in mice. (1)

3. Long Term Toxicity Test for watermelon frost mouth-throat lozenge

Animal species: big white mice (Wistar strain) used in the test are supplied by Animal Room, Academy of Traditional Chinese Medicine in Guang Xi Province.(Certification by Medical Animal Center of China). Animal are 7 weeks old, weight 90-120g, half is male half is female. All mice are randomly divided into four groups: negative, high dose, middle dose, low dose, and males and females are distributed equally in each group. Administering method, dosage, and volume ingested for 12 weeks are listed in following table.

<i>Group</i>	<i>Number</i>	<i>Dose (g/Kg/D)</i>	<i>Volume (ML/100g/BW)</i>	<i>Equivalent clinic dose gram (in human)</i>
1. Negative	n=20	0.00	2.0ml water	0.00
2. High Dosage	n=20	1.8	18% of 10.0ml	107
3. Middle Dosage	n=20	0.9	9% of 10.0ml	53
4. Low dosage	n=20	0.45	4.5% of 10.0ml	26

We fed mice according to above table every day afternoon for 84 days. There were no change in weight($P>0.05$), appetite, hair, feces. There were no death. There were no toxic reactions and abnormality occurred in hematology (such as RBC count, Hb, reticular cells count, WBC count, platelet count and N/L ratio, CT time ($P>0.05$) in three group mice; There were no abnormal blood biochemical index (such as serum in AST, ALT, BUN, Cr., T-BIL, ALB, TOTAL PROTEIN, Cholesterol, GKU in three dose group ($p>0.05$); and there were no pathological damage occurred in the body organs of three dose group by pathologist check, including heart, liver, spleen, lung, kidney, adrenal gland, stomach, small intestine, large intestine, pancreas, pituitary gland, thymus gland, lymph node, testis or ovum etc. All experimental data is performed by Department of Pharmacology, Gui Lin Medical University and Gui Lin San Jin Chinese Pharmaceutical Group, and pathological report is performed by Department of Pathology, Gui Lin Medical University. (1)

4. Impurities, byproducts(limits):

Heavy metal	Lead (Pb)	<0.5ug/g
	Arsenic (As)	0.005ug/g
	Cadmium (Cd)	0.1ug/g
	Mercury (Hg)	0.01ug/g
	Nitrite	ND
	Nitrate	ND
Other toxins	Aflatoxin	9.0ug/Kg
	Mycotoxin	ND

Pesticides such as 666(0.05ug/g) and DDT(0.02ug/g) in 30 sample of watermelon frost mouth-throat extract powder.

5. Microbiological examination of watermelon frost mouth-throat extract powder: ND

Reference:

- 1.Effect of watermelon frost mouth-throat lozenge on pharmacology and Toxicology.
- 2.Dr. William Chang: " reference guide of commonly used herbal formilas".1989

E Proposed tolerances

No tolerances are required to insure the safety of watermelon frost mouth-throat tablet, because of its non-toxic nature.

F. Environmental Assessment

1. Date: Feb 25, 1998

2. Name of Petitioner: Chinese herb Center, Inc.

3. Address of Petitioner:

2025 Eye Street, NW Suite 507

Washington DC 20006

Tel: (202)775-1108

4. Introduction of watermelon frost mouth-throat tablet into Environment

The watermelon frost mouth-throat tablet is manufactured in China for importation into the United States. It is consumed in small quantities in households across the country, under no circumstances this tablet will cause any environmental pollution when discarded by consumer. The tablet is packaged in plastic bottle which can hold 20 tablets, the plastic bottle can be recycled. There are no direct or indirect additives or irradiated herbs used in watermelon frost mouth-throat tablet. The amount of watermelon frost mouth-throat lozenge consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The watermelon frost mouth-throat lozenge is manufactured in China. The manufacture states that their manufacturing process does not result in the emission of any pollutants of concern, and the process does no harm to the environment. The manufacturing process is carried out in conformance with all Chinese laws covering environmental safety.

The certification of watermelon frost mouth-throat lozenge on Non-toxic statement is followed below. "this is to certify that all (watermelon frost lozenge) dietary supplement in this shipment comply with all applicable rules or orders under TSCA (Toxic Substance Control Act) and that I am not offering a dietary supplement for entry in violation of TSCA or any applicable rule or order under TSCA". The certification is issued by China International Exchange Center of Traditional Chinese Medicine and KST Co. The certification is sealed by the China International Exchange Center of Traditional Chinese Medicine and KSD Co.